



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

December 22, 2021

EA-21-103

Mr. Zujia (Justin) Xu, General Manager
Cultilux
325 Funston Street
New Orleans, LA 70123

SUBJECT: NRC INSPECTION REPORT 030-39087/2021-001 AND NOTICE OF VIOLATION

Dear Mr. Xu:

This letter refers to the inspection conducted remotely between January 11 and July 27, 2021. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and with the conditions of your license. The report, Enclosure 2, presents the results of this inspection. A final exit briefing was conducted telephonically with you on November 29, 2021.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations involved the failures to: (1) possess an NRC license prior to distributing byproduct material; (2) restrict distribution to the models authorized on NRC License 17-35464-01E; and (3) submit annual transfer reports required by 10 CFR 32.16(c)(1).

The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you during the telephonic exit meeting on November 29, 2021.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter or (2) request a predecisional enforcement conference (PEC). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response or participate in a PEC. A PEC should be held within 30 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-39087/2021-001; EA-21-103" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the

basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. Your written response, should you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov, within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful in preparing your response. You can find the Information Notice using Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509.

Please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

In addition, the NRC determined, in accordance with the NRC Enforcement Policy, that one Severity Level IV violation of NRC requirements occurred. The violation is cited in Enclosure 1, "Notice of Violation" (Notice) because it was identified by the NRC during the inspection. The violation is regarding your failure to distribute byproduct materials from the location authorized on NRC License 17-35464-01E. By license application, dated August 2, 2021, Cultilux requested to amend the location authorized on the license to correct the noncompliance. On September 28, 2021, the NRC issued Amendment 1 to your license, Agencywide Documents Access and Management System (ADAMS) Accession No. ML21271A221. The circumstances surrounding this violation are described in the enclosed inspection report. Therefore, you are not required to reply to the Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's ADAMS, accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>.

To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff, at 817-200-1455.

Sincerely,



Signed by O'Keefe, Cornelius
on 12/22/21

Mary C. Muessle, Director
Division of Nuclear Materials Safety

Docket No. 030-39087
License No. 17-35464-01E

Enclosures:

1. Notice of Violation
2. NRC Inspection Report 030-39087/2021-001

cc w/Enclosure:

Jeff J. Dauzat, Administrator
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SUBJECT: NRC INSPECTION REPORT 030-39087/2021-001 AND NOTICE OF VIOLATION
DATED DECEMBER 22, 2021

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LRoldanOtero, DNMS		LHowell, OEDO

ADAMS ACCESSION NUMBER - **ML21351A408**

<input checked="" type="checkbox"/> SUNSI Review By: ABB		ADAMS <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available		<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive		Keyword: NRC-002
OFFICE	RIV:MIB	C:MIB	ACES:TL	RIV: RC	OE	NMSS	D: DNMS
NAME	ABBolger	LRoldanOtero	JGroom	DCylkowski	CRiveraDiaz	MBurgess	MCMuessle
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	NFO for MCM
DATE	11/01/21	11/04/21	11/09/21	11/10/21	12/17/21	12/17/21	12/22/21

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Cultilux
New Orleans, Louisiana

Docket No. 030-39087
License No. 17-35464-01E

During an NRC inspection conducted from January 11 and July 27, 2021, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Condition 11 of NRC License 17-35464-01E, dated November 13, 2018, requires, in part, that the licensee may distribute material from the licensee's facility located at 1013 Harimaw CT East, Metairie, Louisiana.

Contrary to the above, from November 27, 2018, to January 11, 2021, the licensee failed to distribute material from the facility located at 1013 Harimaw CT East, Metairie, Louisiana. Specifically, the licensee had been distributing material from 325 Funston Street, New Orleans, Louisiana.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.3.d.9).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance will be (was) achieved, is already adequately addressed on the docket in your application dated August 2, 2021 (ADAMS Accession No. ML21237A318) and the enclosed NRC Inspection Report. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-21-103" and send it to the Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and email it to R4Enforcement@nrc.gov within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

If you contest this enforcement action, provide your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001, with a copy to the Ms. Mary Muessle, Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and email it to R4Enforcement@nrc.gov. A response contesting this enforcement action must be submitted to the NRC within 30 days of the date of the letter transmitting this Notice.

If you respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction. If personal privacy information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information.

If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of

withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy, or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Dated this 22nd day of December 2021

**U.S. NUCLEAR REGULATORY COMMISSION
REGION IV**

Docket No.: 030-39087

License No.: 17-35464-01E

Inspection Report No.: 030-39087/2021-001

EA No.: EA-21-103

Licensee: Cultilux

Location Inspected: 325 Funston Street
New Orleans, LA
(Remote Inspection)

Inspection Dates: January 11 – July 27, 2021

Exit Meeting Date: November 29, 2021

Inspector: Allyce Bolger
Health Physicist
Materials Inspection Branch
Division of Nuclear Materials Safety, Region IV

Approved By: Lizette Roldán-Otero, PhD
Chief, Materials Inspection Branch
Division of Nuclear Materials Safety, Region IV

Attachment: Supplemental Inspection Information

EXECUTIVE SUMMARY

Cultilux NRC Inspection Report 030-39087/2021-001

Program Overview

The U.S. Nuclear Regulatory Commission (NRC) performed a remote initial inspection of Cultilux between January 11 and July 27, 2021. Cultilux is authorized under NRC License 17-35464-01E to distribute byproduct material to persons exempt under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 30.15(a)(8)(iv). The scope of the inspection was to examine the activities conducted under the license and to confirm compliance with the NRC's rules and regulations and with the conditions of the license.

Inspection Findings

The inspection identified three apparent violations of NRC requirements involving the failures to: (1) possess an NRC license prior to distributing byproduct material; (2) restrict distribution activities to the models authorized on NRC License 17-35464-01E; and (3) submit annual transfer reports required by 10 CFR 32.16(c)(1). The inspection additionally identified one Severity Level IV violation involving the failure to distribute from the location authorized on NRC Materials License 17-35464-01E.

Corrective Actions

The first apparent violation had been corrected when Cultilux was issued an NRC license on November 13, 2018. On August 5, 2021, the licensee submitted an amendment request to the NRC to change the distribution location and add the 500W model of lightbulb to NRC License 17-35464-01E. Additionally, in the email transmitting the amendment request, the licensee provided they would be mailing the annual transfer reports, which were received by the NRC on August 12, 2021.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87128)

Cultilux is authorized under NRC Materials License 17-35464-01E to initially distribute byproduct material to persons exempt under Title 10 of the *Code of Federal Regulations* (10 CFR) 30.15(a)(8)(iv). Specifically, the licensee distributes ceramic metal halide (CMH) lightbulbs containing krypton-85 gas.

2 Inspection Overview (IP 87128)

2.1 Inspection Scope

On November 13, 2018, the NRC issued Cultilux a new exempt distribution license. The license was allocated to an incorrect NRC region. An initial inspection was due by November 13, 2019. However, on December 30, 2020, a Region IV staff member identified the administrative error during an audit and immediately assigned an inspector to perform the initial inspection. On January 11, 2021, the NRC began a remote initial inspection to establish the NRC's regulatory oversight for the new licensee. The inspection review continued until July 27, 2021, with electronic document requests and interviews with the licensee's general manager. The purpose of this inspection was to review licensed activities to-date and determine if licensed programs were being conducted in accordance with NRC requirements and the conditions of the license. Inspection activities consisted of an examination of procedures and representative records and interviews with licensee personnel.

2.2 Background

On November 13, 2018, the NRC issued a new license to Cultilux for initial distribution of CMH lightbulbs which contain an arc tube filled with gaseous krypton-85. The lightbulbs are manufactured in China and the licensee was authorized for the initial distribution of device models Spectra X 1000W, 600W, and 315W. The licensee was authorized to distribute the lightbulbs from the facility at 1013 Harimaw CT East, Metairie, Louisiana.

Louisiana is an NRC Agreement State, having regulatory authority to license and regulate byproduct materials within their state, however, exempt distribution activities remain under the purview of the NRC. As the licensee's facility is in Louisiana, the licensee also had a license issued by the Louisiana Department of Environmental Quality (DEQ) for the possession of krypton-85. The Louisiana DEQ possession license was issued on February 2, 2018.

The licensee retained invoices containing records of transfers, including the date, model, and quantity of lightbulbs distributed. While reviewing these records, the inspector identified that Cultilux had begun distributing lightbulbs approximately a month and a half before the issuance of their NRC license. Specifically, on September 24, 2018, Cultilux initially transferred for sale or distribution two units of lightbulbs. As of that date, Cultilux had a possession license with Louisiana DEQ but the license application with the NRC for exempt distribution activities was under review and would not be issued until November 13, 2018.

The licensee stated that it had been under the understanding that distribution activities could commence after their license application had been submitted. The inspector further noted that language in the Louisiana state license authorizing distribution activities may have contributed to the licensee's confusion. Notwithstanding the licensee's misunderstanding and possible confusion, this issue was identified as an apparent violation of NRC requirements, as described below.

3 Observations and Findings

During the remote inspection, three apparent violations and one Severity Level IV violation of NRC requirements were identified as follows:

3.1 Apparent Violation of 10 CFR 30.3(a)

Title 10 CFR 30.3(a) requires, in part, that no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license in accordance with the regulations in Chapter I.

Contrary to the above, on September 24, 2018, the licensee transferred products containing byproduct material without authorization by a specific or general license in accordance with the regulations in Chapter I. Specifically, the licensee distributed two electron tubes containing krypton-85 but did not receive a specific license authorizing initial sale or distribution until November 13, 2018.

The failure to obtain an NRC license prior to distribution was identified as an apparent violation of 10 CFR 30.3(a). (030-39087/2021-001-01)

3.2 Apparent Violation of 10 CFR 30.34(c)

The review of the licensee's invoices identified that Cultilux had distributed a model of 500W lightbulbs that was not authorized on the NRC license. The general manager stated during an interview that the 500W lightbulbs were distributed during a limited release product, between October 19, 2019 and March 12, 2020, to ascertain if that wattage of lightbulb would be marketable. The general manager additionally provided that the internal electron tube containing the krypton-85 in the 500W lightbulbs was exactly the same as in the 600W lightbulbs, containing the same quantity of krypton-85. From the general manager's perspective, the 500W lightbulbs were no different from the 600W lightbulbs and therefore the general manager did not recognize the necessity to amend the license prior to distributing the 500W lightbulb model.

Title 10 CFR 30.34(c) requires, in part, that each person licensed by the Commission pursuant to the regulations in 10 CFR Parts 30 through 36 shall confine his possession and use of the byproduct material to the locations and purposes authorized in the license.

License Conditions 6.A – 9.A of NRC License 17-35464-01E, dated November 13, 2018, authorized the licensee to distribute ceramic metal halide bulbs containing krypton-85 in device models Spectra X 1000W, 600W, and 315W.

Contrary to the above, from October 31, 2019, to March 12, 2020, the licensee failed to limit its distribution of ceramic metal halide bulbs containing krypton-85 to device models

Spectra X 1000W, 600W, 315W. Specifically, the licensee distributed at least 64 ceramic metal halide bulbs containing krypton-85 that are device models Spectra X 500W.

The failure to limit distribution to the device models listed on the license was identified as an apparent violation of 10 CFR 30.34(c) and License Conditions 6.A-9.A. (030-39087/2021-001-02)

3.3 Apparent Violation of 10 CFR 32.16(a)

Since the licensee began distribution activities, it has not submitted any reports to the NRC regarding the transfers of byproduct material made by the licensee. This report is required to be submitted annually and provide information regarding the model(s) distributed and total quantity of radionuclide transferred during a calendar year.

Title 10 CFR 32.16(a) requires, in part, that each person licensed under 10 CFR 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Nuclear Material Safety and Safeguards.

Title 10 CFR 32.16(c)(1) requires, in part, the licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year.

Contrary to the above, from February 1, 2019, to February 1, 2021, the licensee failed to file a report of all transfers of byproduct material with the Director of the Office of Nuclear Material Safety and Safeguards covering the preceding calendar year. Specifically, the licensee, had not filed any reports of transfers of byproduct material that occurred in calendar years 2018, 2019, and 2020.

The failure to submit reports for calendar years 2018, 2019, and 2020 was identified as an apparent violation of 10 CFR 32.16(c)(1). (030-39087/2021-001-03)

3.4 Severity Level IV Violation

The inspection also identified that the licensee was distributing the CMH lightbulbs from a different address than what was authorized on the license. Based on discussions with the licensee and a review of the license applications (the NRC's review of Cultilux's initial application, dated December 5, 2017, was suspended for insufficient information and it was not until Cultilux submitted a revised application, dated August 20, 2018, that the NRC's review progressed) it was identified that during the process of applying for an NRC license, Cultilux had changed locations. Cultilux's application, dated August 20, 2018, contained the updated address, however, the Louisiana DEQ license submitted with the application only authorized possession at Cultilux's former address. Since an NRC exempt distribution license must align with the possession license, the NRC defaulted to the licensee's address listed on the Louisiana DEQ license provided with Cultilux's NRC application.

During the inspection, the licensee personnel stated that they were under the impression that there was an integration between the Louisiana DEQ and the NRC and that communicating license changes to one Agency was sufficient. Despite this confusion, the licensee is still responsible to review the license to ensure its accuracy and to notify the NRC of any deficiencies. In the 2-year period between Cultilux receiving an NRC license and the initial inspection, the licensee failed to identify that the address

authorized on the license was incorrect. Considering the licensee had amended the Louisiana DEQ license to possess byproduct material at the new location and that the NRC license is only authorizing exempt distribution activities, this violation was determined to have little to no radiological or programmatic significance and is being cited in the enclosed Notice (Enclosure 1) as a Severity Level IV violation of Condition 11 of NRC License No. 17-35464-01E. (030-39087/2021-001-04)

4 Corrective Actions

The Apparent Violation of 10 CFR 30.3 was corrected on November 13, 2018, when the NRC issued Cultilux the initial exempt distribution license and there is no further action required of the licensee to come into compliance.

Regarding the distribution of the 500W lightbulbs that are not authorized on NRC Materials License 17-35464-01E, the licensee came into compliance after ceasing the distribution in March 2020, additionally by application dated August 2, 2021, the licensee requested to have the 500W lightbulbs added to the license to ensure compliance in the future if the licensee decided to distribute that material again.

In an email dated August 5, 2021, the licensee provided the common carrier tracking information of the transfer reports mailed to the Director of the Office of Nuclear Material Safety and Safeguards. The tracking information confirmed that the reports were received by the NRC on August 12, 2021. However, the licensee has not provided corrective actions to prevent reoccurrence of the apparent violation of 10 CFR 32.16(a).

In the application dated August 2, 2021, the licensee also requested its license be amended for the correct location of their distribution address and full compliance was achieved when Amendment No. 1 was issued on September 28, 2021. In discussions with the licensee, the inspector had clarified to the licensee that any additional changes to the license would require an amendment.

5 Exit Meeting Summary

On November 29, 2021, a final telephonic exit meeting was conducted with Mr. Xu, General Manager to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report or (2) request a predecisional enforcement conference.

Supplemental Inspection Information

LIST OF PERSONS CONTACTED

Zujia (Justin) Xu, General Manager

INSPECTION PROCEDURES USED

Inspection Procedure 87128: Manufacturing and Distribution of Exempt Products

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-39087/2021-001-01	AV	Failure to have an NRC license before conducting licensed activities (10 CFR 30.3(a))
030-39087/2021-001-02	AV	Failure to contain distribution to the models authorized on the license (10 CFR 30.34(c))
030-39087/2021-001-03	AV	Failure to submit annual transfer reports (10 CFR 32.16(a))
030-39087/2021-001-04	VIO	Failure to distribute from the location authorized on the license (License Condition 11)

Closed

None

Discussed

None

LIST OF ACRONYMS AND ABBREVIATIONS USED

ADAMS	Agencywide Documents Access and Management System
AV	Apparent Violation
CFR	<i>Code of Federal Regulations</i>
CHM	Ceramic metal halide
NRC	Nuclear Regulatory Commission
NOV	Notice of Violation
PEC	Predecisional Enforcement Conference
VIO	Violation